DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

HEALGEN SCIENTIFIC LLC
JOE SHIA
LSI INTERNATIONAL INC
504 EAST DIAMOND AVE. SUITE F
GAITHERSBURG MD 20877

January 27, 2015

Re: K143187
Trade/Device Name: Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card),
Healgen Oxycodone Test (Strip, Cassette, Cup, Dip Card)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DJG
Dated: October 31, 2014
Received: November 5, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143187

Device Name
Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card)
Healgen Oxycodone Test (Strip, Cassette, Cup, Dip Card)

Indications for Use *(Describe)*
Healgen Amphetamine Test is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 1000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen Oxycodone Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug Oxycodone is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. Date: January 21, 2014

2. Submitter: HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX77401

3. Contact person: Jianqiu Fang
HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX77401
Telephone: 713-733-8088
Fax: 713-733-8088
Email: bryan@healgen.com

4. Device Name: Healgen Amphetamine Test (Strip, Cassette, Cup, Dip Card)
Healgen Oxycodone Test (Strip, Cassette, Cup, Dip Card)
Classification:

Product Code	CFR #	Panel
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices:
K052115
First Check Multi Drug Cup 12

6. Intended Use / Indications for Use
Healgen Amphetamine Test is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 1000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen Oxycodone Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a Cut-Off concentration of 100 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug Oxycodone is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for Oxycodone in urine. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

7. Device Description

Healgen Amphetamine Test and Healgen Oxycodone Test are immunochromatographic assays for Amphetamine and Oxycodone. Each assay test is a lateral flow system for the qualitative detection of Amphetamine and Oxycodone (target analyte) in human urine. The products are in vitro diagnostic devices, which come in the form of: Strips, Cassettes, DipCards, or Cups. Each product contains a Test Device (in one of the four formats), and a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen Amphetamine Test and Healgen Oxycodone Test and the predicate device is provided in Table 1 & Table 2.

Table 1: Features Comparison of Healgen Amphetamine Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Amphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	1000 ng/mL	Same

Intended Use Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

Table 2: Features Comparison of Healgen Oxycodone Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Oxycodone	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	100 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

9. Test Principle

Healgen Amphetamine Test and Healgen Oxycodone Test are rapid tests for the qualitative detection of Amphetamine and Oxycodone in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the test has been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

The precision performance of the Healgen Amphetamine and Oxycodone tests was evaluated using 3 lots for each format (Strip, Cassette, Cup, Dip Card) of the device. Each lot was evaluated by a

different operator. The testing consisted of analyzing samples in 2 runs per day for 25 days (n = 50 per lot) and by spiking drug free urine samples to achieve 100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off drug concentrations. The samples were prepared by spiking drug into negative samples. All sample aliquots were blind labeled and randomized and each drug concentration was confirmed by GC/MS. Results are summarized below for each lot and device.

Amphetamine

Strip Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 4	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 5	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 6	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 7	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 8	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 9	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 10	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 11	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 12	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

Oxycodone

Strip Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 4	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 5	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 6	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 7	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 8	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 9	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result / Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot 10	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 11	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 12	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30℃ for 24 months based on the accelerated stability study at 45℃ and real time stability determination at both 4℃ and 30℃.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% cut-off and all negative at and below -25% cut-off for both Amphetamine and Oxycodone. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine Test	Amphetamine	1000
Oxycodone Test	Oxycodone	100

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above cut-off levels. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different formats.

Amphetamine

Acetophenetidin	Fenoprofen	Phenelzine
N-Acetylprocainamide	Furosemide	Phenobarbital
Acetylsalicylic Acid (Aspirin)	Gentisic acid	Phenylephrine-L
Aminopyrine	Hemoglobin	Phenylethylamine
Amitriptyline	Hydralazine	Phenylpropanolamine
Amoxicillin	Hydrochlorothiazide	Prednisolone Acetate
Amobarbital	Hydrocodone	Prednisone
Ampicinine(Ampicillin)	Hydrocortisone	Procaine(Novocaine)
Apomorphine	a -Hydroxyhippuric acid	Promazine
L-Ascorbic Acid	p-Hydroxymethamphetamine	Promethazine
Aspartame	Ibuprofen	Propoxyphene,d-
Atropine	Imipramine	Propranolol
Benzilic acid	Isoxsuprine	Pseudoephedrine HCL
Benzphetamine	Isoproterenol-(+/-)	Quinidine
Bezoic Acid	Ketamine	Quinine
Bilirubin	Labetalol	Ranitidine(Zantac)
Caffeine	Levorphanol	Salicylic Acid
Chloramphenicol	Loperamide	Secobarbital

Chlordiazepoxide HCL	Maprotiline	Serotonin
Chloroquine	Meprobamate	Sulfamethazine
Chlorothiazide	Methadone	Sulindac
Chlorpheniramine	Methoxyphenamine	Temazepam
Chlorpromazine	Methylphenidate	11-Nor-Δ^9-Tetrahydrocannabinol
Cholesterol	Nalbuphine	Tetracycline
Clomipramine	Nalidixic acid	Tetrahydrozoline
Clonidine hydrochloride	Naloxone hydrochloride	Thebaine
Codeine	Naltrexone hydrochloride	Thiamine
Cortisone	Naproxen	L-Thyroxine
Cotinine(-)	Niacinamide	ThioridazineHydrochloride
Creatinine	Nifedipine	Triamterene
Deoxyepinephrine	Norethindrone	Triflupromazine Hydrochloride
Dextromethorphan	Norpropoxyphene	Trimethoprim
Diazepam	Noscapine	Trimipramine
Diflunisal	Oxazepam	Tryptamine
Digoxin	Oxycodone	DL-Tryptophan
Doxylamine	Oxymetazoline	Tyramine
Ecgonine methylester	Papaverine	D/L-Tyrosine
R(-)-Epinephrine	Penicillin	Uric Acid
Erythromycin	Pentobarbital	Verapamil
Estrone-3-sulfate	Perphenazine	Zomepirac
Ethyl-p-aminobenzoate	Phencyclidine	

Oxycodone

Acetophenetidin	Ethyl-p-aminobenzoate	Phencyclidine
N-Acetylprocainamide	Fenoprofen	Phenelzine
Acetylsalicylic Acid (Aspirin)	Furosemide	Phenobarbital
Aminopyrine	Gentisic acid	Phentermine
Amitriptyline	Hemoglobin	Phenylephrine-L
Amoxicillin	Hydralazine	Phenylethylamine
Amobarbital	(+/-)-4-Hydroxyamphetamine HCL	Phenylpropanolamine
D-Amphetamine	Hydrochlorothiazide	Prednisolone Acetate
L-Amphetamine	Hydrocodone	Prednisone
Amphetamine Sulfate	Hydrocortisone	Procaine(Novocaine)
Ampicinine(Ampicillin)	a -Hydroxyhippuric acid	Promazine

Apomorphine	p-Hydroxymethamphetamine	Promethazine
L-Ascorbic Acid	Ibuprofen	Propoxyphene,d-
Aspartame	Imipramine	Propranolol
Atropine	Isoxsuprine	Pseudoephedrine HCL
Benzilic acid	Isoproterenol-(+/-)	Quinidine
Benzphetamine	Ketamine	Quinine
Bezoic Acid	Labetalol	Ranitidine(Zantac)
Bilirubin	Levorphanol	Salicylic Acid
Caffeine	Loperamide	Secobarbital
Chloramphenicol	Maprotiline	Serotonin
Chlordiazepoxide HCL	Meprobamate	Sulfamethazine
Chloroquine	Methadone	Sulindac
Chlorothiazide	Methoxyphenamine	Temazepam
Chlorpheniramine	(+/-)-Methylenedioxyamphetamine(MDA)	11-Nor-Δ^9-Tetrahydrocannabinol
Chlorpromazine	Methylphenidate	Tetracycline
Cholesterol	Nalbuphine	Tetrahydrozoline
Clomipramine	Nalidixic acid	Thiamine
Clonidine hydrochloride	Naloxone hydrochloride	L-Thyroxine
Cortisone	Naltrexone hydrochloride	ThioridazineHydrochloride
Cotinine(-)	Naproxen	Triamterene
Creatinine	Niacinamide	Trifluprom azine Hydrochloride
Deoxyepinephrine	Nifedipine	Trimethoprim
Dextromethorphan	Norethindrone	Trimipramine
Diazepam	Norpropoxyphene	Tryptamine
Diflunisal	Noscapine	DL-Tryptophan
Digoxin	Oxazepam	Tyramine
Doxylamine	Oxymetazoline	D/L-Tyrosine
Ecgonine methylester	Papaverine	Uric Acid
R(-)-Epinephrine	Penicillin	Verapamil
Erythromycin	Pentobarbital	Zomepirac
Estrone-3-sulfate	Perphenazine	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

Amphetamine **(Cut-off=1000 ng/mL)**	**Result** Positive at 1000 ng/mL	**% Cross-Reactivity** 100%
D,L - Amphetamine (Amphetamine Sulfate)	Positive at 1000 ng/mL	100%
Phentermine	Positive at 1250 ng/mL	80%
(+/-)-4-Hydroxyamphetamine HCL	Positive at 600 ng/mL	167%
L-Amphetamine	Positive at 20000 ng/mL	5%
(+/-)-Methylenedioxyamphetamine(MDA)	Positive at 1500 ng/mL	67%
d-Methamphetamine	Positive at >100000 ng/mL	<1%
1-Methamphetamine	Positive at >100000 ng/mL	<1%
ephedrine	Positive at >100000 ng/mL	<1%
3,4-Methylenedioxyethylamphetamine (MDE)	Positive at >100000 ng/mL	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Positive at >100000 ng/mL	<1%

Oxycodone **(Cut-off=100 ng/mL)**	**Result** Positive at 100 ng/mL	**% Cross-Reactivity** 100%
Codeine	Positive at 50000 ng/mL	0.2%
Ethyl Morphine	Positive at 75000 ng/mL	0.1%
Thebaine	Positive at 50000 ng/mL	0.2%
Oxymorphone	Positive at 750 ng/mL	13%
Dihydrocodeine	Positive at 12500 ng/mL	0.8%
Hydromorphone	Positive at >100000 ng/mL	<0.1%
Hydrocodone	Positive at >100000 ng/mL	<0.1%
Morphine	Positive at >100000 ng/mL	<0.1%
Acetylmorphine	Positive at >100000 ng/mL	<0.1%
Buprenorphine	Positive at >100000 ng/mL	<0.1%
Ethylmorphine	Positive at >100000 ng/mL	<0.1%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% cut-off and all

negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

2. Comparison Studies

The method comparison studies for the Amphetamine Test, and the Oxycodone Test were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Amphetamine

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Viewer B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Viewer C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results of Amphetamine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	630	1006	Negative
Viewer A	604	1009	Negative
Viewer A	676	1010	Negative
Viewer B	630	1006	Negative
Viewer B	604	1009	Negative
Viewer B	663	1011	Negative
Viewer C	663	1011	Negative
Viewer C	630	1006	Negative
Viewer C	604	1009	Negative
Viewer C	676	1010	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Viewer B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Viewer C	Positive	0	0	0	14	23
	Negative	10	16	14	3	0

Discordant Results of Amphetamine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	630	1006	Negative
Viewer A	604	1009	Negative
Viewer B	663	1011	Negative
Viewer B	630	1006	Negative
Viewer B	604	1009	Negative
Viewer C	630	1006	Negative
Viewer C	604	1009	Negative
Viewer C	676	1010	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Viewer B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer C	Positive	0	0	0	15	23
	Negative	10	16	14	2	0

Discordant Results of Amphetamine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	630	1006	Negative
Viewer A	676	1010	Negative
Viewer B	663	1011	Negative
Viewer B	630	1006	Negative
Viewer B	604	1009	Negative
Viewer B	650	1015	Negative
Viewer C	630	1006	Negative
Viewer C	676	1010	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Viewer B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results of Amphetamine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	630	1006	Negative
Viewer A	676	1010	Negative
Viewer B	630	1006	Negative
Viewer B	663	1011	Negative
Viewer B	604	1009	Negative
Viewer B	650	1015	Negative
Viewer C	630	1006	Negative
Viewer C	676	1010	Negative
Viewer C	663	1011	Negative
Viewer C	604	1009	Negative

Oxycodone

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Oxycodone Strip

Viewer	**Sample Number**	**GC/MS Result**	**Strip Format Viewer Results**
Viewer A	1256	101	Negative
Viewer A	1243	103	Negative
Viewer A	1211	105	Negative
Viewer B	1256	101	Negative
Viewer B	1211	105	Negative
Viewer C	1256	101	Negative
Viewer C	1243	103	Negative
Viewer C	1211	105	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Oxycodone Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	1256	101	Negative
Viewer A	1243	103	Negative
Viewer A	1211	105	Negative
Viewer B	1256	101	Negative
Viewer B	1243	103	Negative
Viewer B	1211	105	Negative
Viewer C	1256	101	Negative
Viewer C	1243	103	Negative
Viewer C	1211	105	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Oxycodone Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	1256	101	Negative
Viewer A	1243	103	Negative
Viewer A	1211	105	Negative
Viewer B	1211	105	Negative
Viewer B	1256	101	Negative
Viewer C	1256	101	Negative
Viewer C	1243	103	Negative
Viewer C	1211	105	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Oxycodone Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	1256	101	Negative
Viewer A	1243	103	Negative
Viewer A	1211	105	Negative
Viewer B	1256	101	Negative
Viewer B	1243	103	Negative
Viewer B	1211	105	Negative
Viewer C	1256	101	Negative
Viewer C	1243	103	Negative
Viewer C	1211	105	Negative

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons testing each format of the Amphetamine devices and another set of 140 persons testing each format of the Oxycodone devices. Total of 1120 individuals performed the study. A total of 230 females and 330 males tested the Amphetamine samples, and 226 females and 334 males tested the Oxycodone samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

Comparison between GC/MS and Lay Person Results (Amphetamine Strip)

% of Cutoff	Number of samples	Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	2	18	90%
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

Comparison between GC/MS and Lay Person Results (Amphetamine Cassette)

% of Cutoff	Number of samples	Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	1	19	95%
+25% Cutoff	20	1250	19	1	95%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

Comparison between GC/MS and Lay Person Results (Amphetamine DipCard)

% of Cutoff	Number of samples	Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	1	19	95%
+25% Cutoff	20	1250	18	2	90%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

Comparison between GC/MS and Lay Person Results (Amphetamine Cup)

% of Cutoff	Number of samples	Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	250	0	20	100%
-50% Cutoff	20	500	0	20	100%
-25% Cutoff	20	750	1	19	95%
+25% Cutoff	20	1250	20	0	100%
+50% Cutoff	20	1500	20	0	100%
+75% Cutoff	20	1750	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxycodone Strip)

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	25	0	20	100%
-50% Cutoff	20	50	0	20	100%
-25% Cutoff	20	75	2	18	90%
+25% Cutoff	20	125	18	2	90%
+50% Cutoff	20	150	20	0	100%
+75% Cutoff	20	175	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxycodone Cassette)

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	25	0	20	100%
-50% Cutoff	20	50	0	20	100%
-25% Cutoff	20	75	1	19	95%
+25% Cutoff	20	125	19	1	95%
+50% Cutoff	20	150	20	0	100%
+75% Cutoff	20	175	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxycodone DipCard)

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	25	0	20	100%
-50% Cutoff	20	50	0	20	100%
-25% Cutoff	20	75	2	18	90%
+25% Cutoff	20	125	18	2	90%
+50% Cutoff	20	150	20	0	100%
+75% Cutoff	20	175	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxycodone Cup)

% of Cutoff	Number of samples	Oxycodone Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	25	0	20	100%
-50% Cutoff	20	50	0	20	100%
-25% Cutoff	20	75	1	19	95%
+25% Cutoff	20	125	19	1	95%
+50% Cutoff	20	150	20	0	100%
+75% Cutoff	20	175	20	0	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

   Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that the Healgen Amphetamine Test, and Healgen Oxycodone Test are substantially equivalent to the predicate.